## FIRST REGULAR SESSION

## SENATE BILL NO. 111

## 98TH GENERAL ASSEMBLY

INTRODUCED BY SENATOR SCHAAF.

Pre-filed December 3, 2014, and ordered printed.

0661S.01I

ADRIANE D. CROUSE, Secretary.

## AN ACT

To amend chapter 195, RSMo, by adding thereto six new sections relating to a prescription drug monitoring program, with penalty provisions.

Be it enacted by the General Assembly of the State of Missouri, as follows:

Section A. Chapter 195, RSMo, is amended by adding thereto six new

- 2 sections, to be known as sections 195.450, 195.453, 195.456, 195.459, 195.465, and
- 3 195.468, to read as follows:
  - 195.450. 1. Sections 195.450 to 195.468 shall be known and may
- 2 be cited to as the "Missouri Prescription Drug Monitoring Program Act".
- 2. As used in sections 195.450 to 195.468, the following terms shall mean:
- 5 (1) "Controlled substance", the same meaning given such term in 6 section 195.010;
- 7 (2) "Department", the department of health and senior services;
- 8 (3) "Dispenser", a person who delivers a schedule II, III, or IV 9 controlled substance to the ultimate user, but does not include:
- 10 (a) A hospital, as defined in section 197.020, that distributes such 11 substances for the purpose of inpatient care or dispenses prescriptions
- 12 for controlled substances at the time of discharge at such facility;
- 13 **(b)** A practitioner or other authorized person who administers 14 such a substance; or
- 15 (c) A wholesale distributor of a schedule II, III, or IV controlled substance;
- (4) "Patient", a person who is the ultimate user of a drug for whom a prescription is issued or for whom a drug is dispensed, except that "patient" shall not include a hospice patient enrolled in a Medicare-certified hospice program who has controlled substances

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- 21 dispensed to him or her by such hospice program;
- 22 (5) "Prescription drug monitoring program" or "PDMP", a 23 program established by the department under sections 195.450 to 24 195.468, monitoring the dispensing of all Schedule II, III, or IV 25 controlled substances";
- 26 (6) "Schedule II, III, or IV controlled substance", a controlled substance that is listed in schedules II, III, or IV of the schedules provided under this chapter or the federal Controlled Substances Act, 29 21 U.S.C. Section 812.
- 3. Notwithstanding any other law to the contrary, the provisions of sections 195.450 to 195.468 shall not apply to persons listed under chapter 340.
  - 195.453. 1. Subject to appropriations, the department of health and senior services shall establish and maintain a program monitoring the dispensing of all schedule II, III, or IV controlled substances by all professionals licensed to dispense such substances in this state.
- 2. The department shall maintain a database of prescription 5 controlled substances dispensed in this state using an existing data 6 aggregation platform through the state data center within the office of administration. The department shall ensure the privacy and security of the personal information of the citizens of this state while only aggregating necessary and appropriate information related to the prescribing or dispensing of prescription schedule II, III, or IV 12 controlled substances. The aggregated information from each dispenser 13 data source shall remain segregated from any other data source and 14 shall not be commingled with data from any other source. The 15 information contained on the database shall not be entered onto any other database outside the control of the department. The information shall not be entered into the national prescription drug monitoring 1718 database.
  - 3. The department is authorized to contract with any other agency of this state or any other state with a private vendor, or any state government that currently runs a prescription monitoring program for hardware or software. Any contractor shall comply with the provisions regarding confidentiality of prescription information under section 195.468.

195.456. 1. Each dispenser at the time of filling a prescription

- 2 controlled substance shall submit to the department by electronic
- 3 means information regarding each dispensation of controlled
- 4 substances included in subdivision (6) of subsection 1 of section
- 5 195.450. The information submitted for each prescription shall include,
- 6 but not be limited to:
- 7 (1) The pharmacy federal Drug Enforcement Administration 8 (DEA) number;
- 9 (2) The date of the dispensation;
- 10 (3) As to the prescription:
- 11 (a) The prescription number;
- 12 (b) Whether the prescription is new or a refill;
- 13 (c) The prescriber's name, address, telephone number, and DEA 14 or National Identifier (NPI) number;
- 15 (d) The date the prescription is issued by the prescriber;
- 16 (e) The source of payment for the prescription;
- 17 (4) The National Drug Code (NDC) for the drug dispensed;
- 18 (5) The number of days' supply of the drugs;
- 19 (6) The quantity, form, and strength to be dispensed;
- 20 (7) The patient identification number, including but not limited 21 to, any one of the following:
- 22 (a) The patient's driver's license number;
- 23 (b) The patient's government-issued identification number; or
- 24 (c) The patient's insurance cardholder identification number;
- 25 and

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- 26 (8) The patient's name, address, and date of birth.
- 27 2. Each dispenser shall submit the information in accordance
- 28 with transmission standards established by the American Society for
- 29 Automation in Pharmacy, or any successor organization.
- 30 3. The department may provide data in the PDMP database to the following persons:
- 32 (1) An individual who requests his or her own dispensation 33 monitoring information in accordance with state law;
- 34 (2) Any state board charged with regulating a professional that 35 has the authority to prescribe or dispense controlled substances that 36 requests data related to a specific professional under the authority of 37 that board;
  - (3) Local, state, and federal law enforcement or prosecutorial

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39 officials, both in-state and out-of-state engaged only in the administration, investigation, or enforcement of the laws governing licit drugs based on a specific case and under a subpoena or court order: 42

- 43 (4) A judge or other judicial authority under a subpoena or court 44 order; and
- (5) Personnel of the department of health and senior services for 45 the administration and enforcement of sections 195.450 to 195.468. 46
- 47 4. The department may provide data to public or private entities for statistical, research, or educational purposes after removing 49 information that could be used to identify individual patients, 50 prescribers, dispensers, or persons who received dispensations from 51 dispensers.
- 52 5. (1) The department may issue a waiver to a dispenser that is unable to submit dispensation information by electronic means. Such 53 waiver may permit the dispenser to submit dispensation information by telephone or other secure means, provided all information required 55 in subsection 1 of this section is submitted in such alternative format 56 as soon as practicable. 57
- (2) The department may grant an extension to dispensers who are temporarily unable to electronically submit the dispensation information required in subsection 1 of this section in accordance with the time frame established in subsection 2 of this section due to unforseen circumstances. In cases where an extension is granted, dispensers shall be responsible for reporting the required data in a 64 subsequent file.
- 195.459. 1. No dispenser shall have access to the PDMP database established under sections 195.450 to 195.468, but shall only transmit information to be included into it. All dispensers shall have a prominently posted sign in bold letters stating "ALL CONTROLLED SUBSTANCE PRESCRIPTIONS SHALL BE REPORTED TO THE 5 BUREAU OF NARCOTICS AND DANGEROUS DRUGS AND SCREENED 6 FOR VIOLATIONS". 7
- 2. A dispenser shall wait no longer than five minutes for a reply 8 from the department confirming that a similar prescription had not been dispensed within the most recent day's supply limit from another dispenser. After the five minute limit, the dispenser may proceed to

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dispense the medication. If the department responds with a message that there was such a transaction within the day's supply limit, the dispenser shall not dispense the medication before resolving the issue with the patient's physician or the department, or both.

- 3. If a dispenser or an employee of the dispenser has reasonable cause to believe that the transaction would be a violation of the law, the dispenser may call or email the department on numbers or email addresses provided by the department. If after reviewing its PDMP database and the national prescription drug monitoring database, the department has reasonable cause to believe that the transaction is in violation of law, the department shall respond as rapidly to the dispenser as possible in order to prevent the transaction. If the response is not timely and the transaction is concluded before a response by the department, the dispenser may be required to assist law enforcement with an investigation.
- 4. No licensed dispenser following the provisions of sections 195.450 to 195.468, shall be subject to discipline by the Missouri Board of Pharmacy or by any other state agency for acting in good faith to fill a prescription for a controlled substance, nor for acting outside of these rules in an emergency.

195.465. 1. When a dispenser electronically sends a prescription to be added to the PDMP database, the department shall electronically screen its PDMP database and the national prescription drug 4 monitoring database to determine if the prescription may be properly dispensed and that a similar medication has not been dispensed within the allowable day's supply limits set by the department. If no concern is detected, the department shall electronically and automatically issue a communication to the dispenser that no concern was detected. If a concern is detected, a staff member of the department shall review the record and if possible, communicate in real time with the dispenser to 11 resolve the issue. If after staff review, it appears that there is 12 reasonable cause to believe that a person has obtained a prescription fraudulently from more than one prescriber, the department shall 13 contact the prescribers and request copies of medical records concerning the prescriptions of concern. The prescribers shall provide 15 the records, if possible, by fax or electronically. If after department 16 review of the provided records, it is clear that a person has obtained

prescriptions under false pretenses, the entire matter shall be referred to the appropriate law enforcement or local prosecuting attorney for action.

21 2. The department shall promulgate rules setting forth the 22 procedures and methods of implementing sections 195.450 to 195.468. Any rule or portion of a rule, as that term is defined in section 23 536.010, that is created under the authority delegated in this section 24shall become effective only if it complies with and is subject to all of 25the provisions of chapter 536 and, if applicable, section 536.028. This 26section and chapter 536 are nonseverable and if any of the powers 2728 vested with the general assembly pursuant to chapter 536 to review, to delay the effective date, or to disapprove and annul a rule are 29subsequently held unconstitutional, then the grant of rulemaking 30 authority and any rule proposed or adopted after August 28, 2015, shall 31 be invalid and void.

195.468. 1. The department shall annually provide to the general assembly a report as to the number of controlled substances dispensed, broken down by drug, the number of incidents of fraudulent prescriptions identified and any other pertinent information requested by the general assembly.

- 6 2. Beginning August 28, 2017, the department shall discard the 7 data obtained from PDMP database one year from the date the data was 8 obtained under sections 195.450 to 195.468.
- 3. A person authorized to have dispensation monitoring information under sections 195.450 to 195.468 who knowingly discloses such information in violation of sections 195.450 to 195.468 or who uses such information in a manner and for a purpose in violation of sections 195.450 to 195.468 is guilty of a class A misdemeanor.

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